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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,078	03/15/2004	Krzysztof Palczewski	029060-000200US	9475

70680 7590 08/25/2010

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EXAMINER	
HUANG, GIGI GEORGIANA	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
08/25/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/801,078	PALCZEWSKI ET AL.	
	Examiner	Art Unit	
	GIGI HUANG	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *52-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *52-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/14/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The response filed June 7, 2010 has been received, entered and carefully considered. The response affects the instant application accordingly:

   a. Claim 16-20, 35-37, 49-51 has been cancelled.

   b. Claim 52-71 has been added.

2. Claims 52-71 are pending in the case.

3. Claims 52-71 are present for examination.

4. All grounds not addressed in the action are withdrawn or moot.

5. New grounds of rejection are set forth in the current office action.

6. The amendments to the specification have been accepted.

New Grounds of Rejection and Objection

Due to the amendment of the claims the new grounds of rejection and objection are applied:

Claim Objections

7. Claim 61 is objected to because of the following informalities: The word "he" appears to misspelled and meant to be "The". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 52, 54-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims are directed to a synthetic retinoid that is a derivative of 9-dis retinal reciting that the compound is capable of inducing the *in vivo* folding and stabilization of a P23H mutant opsin protein to form visual pigment after intraocular injection into an eye of a transgenic mouse expressing the human P23H mutant opsin protein. The specification has not described what degree of derivation for the compounds is envisioned or a structure/function relationship for the derivatized compounds Applicant was in possession of at the time of the invention. The claims as written extends to any number of possible compounds as a compound can be derivatized to any number of degrees as addressed in the indefinite rejection below and hypothetically any compound could have any degree of the capacity, as there is no clear description for the scope or structure/function relationship for the compounds as claimed and extends to compound yet to be made wherein Applicant would not be in possession of these compounds at the time of the invention.

9. Claims 53, 63-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims recite the conditional recitation of

"if of R_1, R_2, R_4, R_5, R_6, R_8, and R_9 is hydrogen, then R_3 and R_7 are not both methyl" which is not supported by the specification. The explicit recitation and exclusion is not described in the specification as written. This is a new matter rejection.

10. Claims 53, 63-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The claims are directed to treating a human with the loss of photoreceptor function due to expression of a mutant human opsin protein with a substitution of Proline23 by Histidine (P23H mutant opsin protein) wherein there is no description as to what conditions are encompassed by this recitation and which conditions present this loss of photoreceptor function as a result of this particular (P23H) opsin mutation other than a particular subgenus of retinitis pigmentosa-the autosomal dominant retinitis pigmentosa due to the P23H mutation of the opsin protein, which is the most common form of retinitis pigmentosa (about 10% of the cases). There is no other condition described in the specification with this particular mutation.

11. Claims 52-71 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for particular retinal compounds addressed below, it does not reasonably provide enablement for all the compounds embraced by the scope of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

> The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to a method of treating directed to treating a human with the loss of photoreceptor function due to expression of a mutant human opsin protein with a substitution of Proline23 by Histidine (P23H mutant opsin protein) such as autosomal dominant retinitis pigmentosa from P23H, with the compounds generally derived from 9 cis-retinal (claim 52) and those recited in the formula of claim 53. Thus, the claims taken together with the specification imply that any compound (claim 52) as any compound can be derived from 9-cis retinal (addressed in the rejections above and below) and all the compounds in the formula present in claim 53 can treat these retinal conditions.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Ebrey et al. (Properties of Several Sterically Modified Retinal Analogs and Their Photosensitive Pigments) teaches that substitution at the 14 position of the 9-cis retinal (R8 of the claimed formula) with methyl coupled with opsin and produced pigments that where relatively close in photosensitivity to the original 9-cis retinal. However, the 13-desmethyl-14-methylretinal form (claimed formula:R3=methyl, R6=methyl, remaining R's =H) while coupling with the opsin to form a pigment, the coupled was so weak as to only produce small amount of pigment despite large accesses of chromophore and in some preparation almost no pigment was formed indicating that pigment formation with the 13-desmethyl-14-methylretinal form. Ebrey also specifically addresses that simple substitution of the 15 position (R9 of the instant claimed formula) with methyl for hydrogen for 9-cis retinal was unable to form a pigment. This as also the case with the retinals in general for substitution of the 15postiion (R9 of claim 122 of the formula). The lack of reactivity is presumed steric hindrance.

Liu et al. (The Nature of Restriction in the Binding Site of Rhodopsin. A Model Study) addresses that fluorine substitution of 9-cis on the 12 position (R6 of claimed formula) produced a good yield of stale functional pigments. 12postion substitution with methyl and chlorine modestly produced stable pigments; however ring fused retinals filed to form pigments.

Asato et al. (Fluorinated Rhodopsin Analogues from 10-Fluoro- and 14-Fluororetinal) addressed that fluorine substitution on the 10 and 12 position of 9-cis retinal (R4 and R6 of claimed formula) behaved similar to the parent retinal produced

stable pigments had similar absorption profile of rhodopsin which is not unexpected due to the biosterism of hydrogen and fluorine.

Accordingly, the art addresses the high unpredictability of the retinals for forming pigments as that the claimed compound formula while enabled for certain compounds such as 9-cis-10-F-retinal, 9-cis-10-methyl-retinal, 9-cis-12-F-retinal, 9-cis-12-methyl-retinal, 9-cis-12-Cl-retinal, 9-cis-14-F-retinal, and 9-cis-14-methyl-retinal per the art; is not enabled for the scope of the claimed formula as substitutions on the 15 position do not form pigments needed for treatment of the condition, and the 13-desmethyl-14-methylretinal form is not likely to be utilized for therapy as the pigment is poorly formed if at all and difficult despite the amount of chromophore to provide an adequate amount for therapeutic levels.

(5) The relative skill of those in the art:

The skill of one in the art is high.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided only general guidance and a general disclosure of certain retinals and its use. The examples however are for the 11-cis-7ring retinals, not the 9-cis retinals. The art has provided enablement for particular compounds including 9-cis-10-F-retinal, 9-cis-10-methyl-retinal, 9-cis-12-F-retinal, 9-cis-12-methyl-retinal, 9-cis-12-Cl-retinal, 9-cis-14-F-retinal, and 9-cis-14-methyl-retinal.

However, the specification does not provide evidence of enablement for the full scope of the compounds based on the showing of only the 11-cis-7-ring retinals which vary widely in enablement from the 9-cis form as demonstrated by the high level of unpredictability and enablement between retinal types (e.g. 9-cis, all-trans, 11-cis) as addressed in the art above, but also the high degree of unpredictability within the grouping on even single substitutions per compound along the chain as seen in the art above wherein there is no showing of which 9-cis retinal forms of claim 53 for example, are enablement as the art addresses that a number of them do not form pigment.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to the difficulty attaining retinals that would produce sufficient yields of stable pigment and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 52, 54-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “derivative” is indefinite as it unclear is

encompassed by the term and given the form any number of compounds given an infinite number of chemical reactions, the compounds and be anything and thereby it is unclear what is envisioned for the invention. It does not allow one of skill in the art to know the metes and bounds of the invention. For purposes of prosecution compounds of the formula in claim 53 will be applied to further prosecution.

13. Claims 53, 63-71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are directed to treating a human with the loss of photoreceptor function due to expression of a mutant human opsin protein with a substitution of Proline23 by Histidine (P23H mutant opsin protein) but it is unclear what conditions are encompassed by this recitation and which conditions present this loss of photoreceptor function as a result of this particular (P23H) opsin mutation other than a particular subgenus of retinitis pigmentosa-the autosomal dominant retinitis pigmentosa due to the P23H mutation of the opsin protein, which is the most common form of retinitis pigmentosa (about 10% of the cases). It does not allow one of skill in the art to ascertain the metes and bounds. For purposes of prosecution, the recitation is viewed as the autosomal dominant retinitis pigmentosa due to the P23H mutation of the opsin protein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 52-54, 60,62-63, 69,71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapple et al. (Looking at protein misfolding neurodegenerative disease through retinitis pigmentosa) in view of Asato et al. (Fluorinated Rhodopsin Analogues from 10-Fluoro- and 14-Fluororetinal).

Chapple et al. teaches that retinitis pigmentosa is the most common cause of inherited blindness. The most frequent mutation and misfolding mutation in rhodopsin is the proline to histidine change at residue 23 (P23H). Chapple et al. teaches that 9-cis retinal can improve folding of the mutant rhodopsin in T17M mutant opsin and in P23H mutant opsin allowing improved movement of opsin to reach the plasma membrane, whereby the retinoid can be used as a 'chemical' chaperone to stabilize the folding of the mutant opsins shifting the equilibrium toward functional proteins. Chapple teaches that is known in the art that Vitamin A has some therapeutic value in retinitis pigmentosa. Chapple also teaches that while the trial was not focused on patient with the these misfolded mutations, if they had, the clinical outcomes may have been even better and that further investigation of these methods may lead to therapies for the misfolded protein disease and other conditions.

Chapple does not expressly teach an example with administration to a human. Chapple does however, teach the benefit of 9-cis retinal in improving the P23H mutant protein to forming functional opsin and teaches that had the trial been with patients with the misfolded mutants, the outcome could be even better, wherein Chapple already

has described utilizing the 9-cis retinal on human patients with the misfolded P23H opsin.

It would have then been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize the 9-cis retinal for a patient with P23H retinitis pigmentosa as described by Chapple, and produce the instant invention. It would have been obvious to approach this next step and one of skill in the art would be motivated to do so, as it is already described by Chapple and pursue this next phase as typical in the art to move from animal/lab models to human subjects with the condition as the progression to developing an effective, safe, and therapeutic treatment for any condition. It is also obvious and known by one of skill in the art that the active (9-cis-retinal) would have to be in a pharmaceutically acceptable carrier as an active cannot be given without a carrier which is the motivation if one wants to administer any active. It is noted that when the active is administered as claimed, the mechanism of action is intrinsic to the composition and mode of administration.

Chapple does not expressly teach incorporation of the retinals in the claimed formula such as 9-cis-10-F-retinal and 9-cis-12-F-retinal, but does implicitly teach the use of 9-cis retinal for P23H retinitis pigmentosa as addressed above.

Asato et al. (Fluorinated Rhodopsin Analogues from 10-Fluoro- and 14-Fluororetinal) addressed that fluorine substitution on the 10 and 12 position of 9-cis retinal (R4 and R6 of claimed formula) behaved similar to the parent retinol pigments had similar absorption profile of rhodopsin which is not unexpected due to the biosterism of hydrogen and fluorine.

It would have been obvious to one of skill in the art at the time of the invention to substitute 9-cis-10-F-retinal or 9-cis-12-F-retinal, for 9-cis retinal as suggested by Asato, and produce the invention as simple substitution of a structurally similar and functional compound is obvious and routine in the art; particularly as that the 10- and 14-fluorine isomers of 9-cis retinal behaved very similar to the parent 9-cis retinal and formed stable rhodopsin pigments which was not unexpected as the hydrogen and fluorine are similar sterically as addressed by Asato. It desirable for artisans and manufactures to have functionally equivalent compounds to substitute the component (retinal) particularly as they are positional isomers formed from known biosteric substitution methods when motivated by pricing, availability, or desired properties of the retinal used to produce the final product.

15. Claim 55, 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapple et al. (Looking at protein misfolding neurodegenerative disease through retinitis pigmentosa) in view of Asato et al. (Fluorinated Rhodopsin Analogues from 10-Fluoro- and 14-Fluororetinal) as applied above, in view of Grant et al. (Treatable forms of Retinitis Pigmentosa Associated with Systemic Neurological Disorders-Abstract).

The teachings of Chapple et al. in view of Asato are addressed above.

Chapple in view of Asato does not expressly teach oral administration of these compounds but does teach that high does of vitamin A (a retinoid) had been show to be therapeutic in retinitis pigmentosa (Page 13 second column).

Grant et al. teaches that oral Vitamin A therapy has been proven to be useful in the treatment of the common forms of retinitis pigmentosa (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize oral delivery, as suggested by Chapple and Grant, and produce the instant invention as it is obvious to use a known and effective mode of retinal delivery that is effective for retinitis pigmentosa such as oral delivery as addressed by Grant and Chapple as the both teach that retinals such as vitamin A can be given for retinitis pigmentosa and it given in oral doses to be effective for its common form which encompass the P23H form as taught by Chapple. It is desirable to use a mode of administration to deliver these compounds as it has already been shown to be able to deliver retinals to the posterior portion of the eye (retina) to effectively treat this difficult condition with a reasonable expectation of therapeutic delivery and success.

16. Claim 56-59, 61,65-68, 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapple et al. (Looking at protein misfolding neurodegenerative disease through retinitis pigmentosa) in view of Asato et al. (Fluorinated Rhodopsin Analogues from 10-Fluoro- and 14-Fluororetinal) as applied above, in view of Lang (Ocular drug delivery conventional ocular formulations) and Geroski et al. (Drug Delivery for Posterior Segment Eye Disease).

The teachings of Chapple et al. in view of Asato are addressed above.

Chapple in view of Asato does not expressly teach eye drops, intraocular injection, and periocular injection.

Lang teaches that there are commonly known dosage forms for ocular drug delivery including solutions (eye drops) , suspensions (eye drops), and injectables (Abstract, Table 1).

Geroski et al. is presented merely to demonstrate that there are known types of ophthalmic injections to one of skill in the art for drug delivery including intraocular and periocular (Page 961, second column).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize known modes of ophthalmic drug delivery including drops and injections such as periocular and intraocular, as suggested by Lang and Geroski, and produce the instant invention. It would be obvious to utilize any of the known and conventional modes of administration forms to deliver any active for an eye condition including drops and injections depending on the therapeutic profile desired as these are well known conventional modalities in the art. It is noted that when the active is administered as claimed, the mechanism of action is intrinsic to the composition and mode of administration.

One of ordinary skill in the art would have been motivated to do this because it is desirable to utilize known modes of administration and have different forms of administration to affect the condition to be treated in the most effective manner and therapeutic profile desired for the patient.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 52-71 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/817015. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds and conditions of the instant application are species encompassed by the more generic retinoid and degenerative disease of the conflicting claim in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

18. Applicant's arguments with respect to the previous claim rejections have been considered but are moot in view of the new amendments to the claims.

19. In regards to Applicant's assertion that the Chapple reference did not qualify under 102(b) and is understood to be under 102(a), the Chapple reference was utilized for a 103 rejection with qualification as a 102(a) date. In regards to Applicant's assertion that Ms. Hansford statement does not indicate first hand knowledge of the publication process at the time period, this is not persuasive as there is no evidence presented by Applicant to contradict Ms. Hansford's statement to the availability of the reference. Ms. Hansford is the publisher of the publication and is aware of the normal and expected publication process for her particular publication where she is very clear that the issue would normally be published in the first week of March with the online publication some weeks afterwards. The reference still qualifies as prior art.

Conclusion

20. Claims 52-71 are rejected.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, FEREYDOUN SAJJADI can be reached on 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GiGi Huang/
Examiner, Art Unit 1617
/Zohreh A Fay/

Primary Examiner, Art Unit 1627